REMARKS

Rejections under 102(b)

The Examiner has rejected Claims 1-3 and 20 under 35 U.S.C. 102 (b) as being anticipated by Marinkovich et al. (US 4,558,013; hereafter referred to as Marinkovich). Specifically, the Examiner states Marinkovich teach an apparatus comprising coated test regions. The coated test regions can be spots coated with different binding conjugates for immunoglobulins whose presence is to be detected and measured. Marinkovich also teaches a control spot coated directly with IgE itself.

Applicants respectfully disagree with the Examiner's assertion that Marinkovich anticipates the instant claim set. As noted by the Examiner, Marinkovich teaches an apparatus comprising spots in the form of threads. Marinkovich also teaches each thread is coated with a binding conjugate for the immunoglobulin whose presence is to be detected. The key point to be noted is that Marinkovich teaches coating each thread with a different binding conjugate (e.g. allergen). The Examiner's attention is directed to column 2, lines 8-10 of Marinkovich which state the carrier includes a "plurality of test regions, each coated with a different component..." Spotting the allergens individually allows the device to identify specific allergens to which a patient makes IgE. In contrast to the teachings of Marinkovich, the instant Application teaches a device spotted with a mixture of allergens. The mixture contains any suitable number of allergens, greater than one, that allows for the appropriate identification of a patient population. As explained in the instant specification, for example, on page 5, lines 25-26, through page 8, lines 1-11, the use of a carefully selected mixture of allergens enables the device to contain a minimum number of spots while still identifying a great majority of patients with IgE-mediated allergic disease. From this it is clear that using a mixture of allergens is a key component of the instant invention . Thus, the formats in which the allergens are spotted in the instant invention and that of Marinkovich are completely different. In view of the above, Applicants request withdrawal of the rejection under 102(b) in view of Marinkovich.

The Examiner has rejected Claims 1-4, 9-11 and 20-22 under 35 U.S C. 102 (b) as being anticipated by Hubscher et al. (US 6,528,325; hereafter referred to as Hubscher). Specifically, the Examiner states Hubscher teaches a lateral flow immunoassay device capable of detecting

IgE antibody to many allergens coated sequentially on a strip. Hubscher also teaches a positive control comprising anti-IgE antibodies. The Examiner further states Hubscher teaches the device can be used to test for one or more different allergens using multiple strips next to each other where the strips can contain one or more allergen lines.

The Applicants respectfully disagree with the Examiner's assertion the Hubscher anticipates the instant invention. As noted by the Examiner, Hubscher teaches allergens coated sequentially on a strip. However, Hubscher is concerned with determining if IgE to a particular allergen is present. Therefore, Hubscher teaches coating spots with one individual allergen. As discussed above with regard to Marinkovich, the instant Application teaches using a mixture of allergens. The use of a mixture of allergens is a key feature of the instant invention in that it allows the device to contain a minimum number of spots while still identifying a great majority of patients with IgE-mediated allergic disease; see above and also, for example, the specification at page 5, lines 25-26, through page 8, lines 1-11. Applicants contend the use of a mixture of allergens is not the same as the use of individually spotted allergens and therefore, Applicants respectfully request withdrawal of the rejection under 102(b) in view of Hubscher.

Rejections under 103(a)

The Examiner has rejected Claims 25-27 under 35 U.S.C. 103(a) as being unpatentable in view of Hubscher et al. (US 6,528,325; hereafter referred to as Hubscher). Specifically, the Examiner states Hubscher teach a lateral flow device which can be used for the detection of allergen specific IgE antibodies in human or animal serum. The Examiner contends that while Hubscher did not specifically teach the animal serum could be canine, feline or equine, the use of such serum would have been obvious to one of skill in the art since they represent examples of animal serum used in normal experimental techniques known in the art.

Applicants respectfully disagree with the Examiner's assertion the instate claims are obvious in light of Hubscher. It well established that in order to establish a *prima facie* case of obviousness, the Examiner must present evidence, preferably in the form of some teaching in the applied prior art or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to modify the applied reference in the proposed manner; (see *Ex. Parte Levengood*, 28 USPQ 2d 1300, BdPatApp&Int, 1993). Even when obviousness is based on a single reference, there must be a showing of a suggestion or motivation to modify the

teachings of that reference (*In re Kotzab*, 55 USPQ 2d 1313, CAFC, 2000) Furthermore, it is equally clear that the prior art reference must teach all of the claim limitations. Applicants assert that these two conditions have not been met in the instant case. The Examiner states that in view of Hubscher, it would have been obvious to one of skill in the art to use the instant invention to detect canine, feline or equine allergen-specific antibodies. However, while Hubscher does teach the use of animal serum, Hubscher fails to teach detection of allergen-specific IgE in animal serum using a device comprising a mixture of allergens. The limitation of a mixture of allergens, clearly present in the instant claims, is completely lacking from the teaching of Hubscher. As noted *supra*, Hubscher teaches a device in which the binding conjugates are spotted individually. The Examiner has failed to provide any evidence showing Hubscher teaches or suggests the desirability of pooling the binding conjugates and spotting them together. Therefore, based on Hubscher, one skilled in the art would not have been motivated to use a mixture of allergens. In fact, the use of an allergen mixture would be contrary to the nature of the invention of Hubscher since it would interfere with the ability to identify whether or not IgE to a specific allergen is present. This ability is a key feature of Hubschers invention. In view of this, Applicants contend the Examiner has failed to establish a prima facie case of obviousness and respectfully request withdrawal of the rejection under 103(a) in view of Hubscher.

The Examiner has rejected Claims 28-29 under 35 U.S.C. 103(a) as being unpatentable over Marinkovich et al. in view of Mita et al (hereafter referred to as Mita). The Examiner has also rejected claims 28-29 as being unpatentable over Hubscher in view of Mita. Specifically, the Examiner states it would have been obvious to include anti-IgE antibodies in the device of Marinkovich or the device of Hubscher as a positive control in order to detect IgE for allergens.

Applicants respectfully disagree that the instant invention is obvious in view of Marinkovich or Hubscher combined with Mita. As noted *supra*, it is well established that in order to establish a *prima facie* case of obviousness, the Examiner must present evidence, preferably in the form of some teaching in the applied prior art or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to modify or combine the applied references in the proposed manner; (see *Ex. Parte Levengood*, 28 USPQ 2d 1300, BdPatApp&Int, 1993). Furthermore, it is equally clear that the prior art reference must teach all of the claim limitations. Applicants have already discussed the shortcomings of

Marinkovich and Hubscher as prior art; in particular, neither of these references teach the use of a mixture of allergens but rather they teach spotting allergens individually. Applicants assert that Mita does nothing to remedy this lack of teaching. Therefore, neither Marinkovich, Hubscher nor Mita teach the limitation of a mixture of allergens. Moreover, none of these references even suggest the benefit or desirability of using such a mixture. Thus, nothing in the prior art, alone or combined, would motivate one skilled in the art to use a mixture of allergens as Applicants have done in the instant invention. In fact, as discussed *supra*, spotting allergens as a mixture would be contrary to the nature of the inventions of Marinkovich and Hubscher since doing so would interfere with the ability to identify whether or not IgE to a specific allergen is present. In view of this, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. 103(a) in view of the combination of Marinkovich and Mita and the combination of Hubscher and Mita.

CONCLUSION

All of the pending claims are believed to be in condition for allowance. In the event the Examiner has any questions regarding this Application, the Examiner is invited to contact the undersigned representative at (970) 493-7272.

Respectfully submitted,

Dated: January 19, 2005

By: Richard J. Stern

Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
1613 Prospect Parkway
Fort Collins, Colorado 80525
Telephone: (970) 493-7272
Facsimile: (970) 491-9976